

K071560

FEB - 8 2008

### 510(K) SUMMARY

510(k) Applicant: Ventus Medical, Inc.  
1301 Shoreway Road, Suite 340  
Belmont, CA 94002  
Menlo Park, CA 94025  
(650) 632-4199 (phone)  
(650) 632-4198 (fax)

Contact: Cindy Domecus, R.A.C. (US & EU)  
Domecus Consulting Services LLC  
(650) 343-4813 (phone)  
(650) 343-7822 (fax)

Date Summary Prepared: February 7, 2008

Name of Device: Provent™ Professional Sleep Apnea Therapy

Common Name: Intraoral device

Classification Name: Intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea (21 CFR 872.5570)

Predicate Device: Predicate devices included in the 510(k) Notification are noted in the below table of comparison to predicate devices. A few examples are cited below.

- Oasys Oral Airway System, K030440
- REMstar Auto M-Series with AFLEX Series CPAP System (K063830)
- Breas iSleep 20i System (K063476)
- BiPAP Synchrony (K071509, K070328, K063533)
- BiPAP Auto SV (K063540)
- BiPAP Focus (K053168)

## Device Description

The Provent device is placed just inside the nostrils. The device directs expiratory flow through selected pathways, which increases intranasal pressure similar to the expiratory portion of the breathing cycle during CPAP use.

## Indications for Use

For the treatment of obstructive sleep apnea (OSA).

## Comparison to Predicate Devices:

The below table shows a comparison of the Provent device to its predicates.

	Provent Device	Oasys Oral Airway System, KO30440	EMS PEEP Valves, K983920	Intraoral devices, cervical pillows, CPAP/BiPAP devices and accessories, RF, and laser devices
Indications for Use	The Provent device is indicated for the treatment of obstructive sleep apnea (OSA).	The OASYS Oral Airway System is intended to reduce or alleviate snoring and obstructive sleep apnea, OSA.	An accessory to provide positive end expiratory pressure breathing capabilities to manual resuscitator, therapeutic CPAP systems, ventilator circuits...	As noted in above tables, all these device categories have been classified as Class II and cleared for use in OSA via the 510(k) route.
Product Code	LWF, BZD, MNT, MNS	LRK, LWF	BYE	LRK, LOZ, MYB, BZD, MNT, MNS, GEX, GEI

	<b>Provent Device</b>	<b>Oasys Oral Airway System, K030440</b>	<b>EMS PEEP Valves, K983920</b>	<b>Intraoral devices, cervical pillows, CPAP/BiPAP devices and accessories, RF, and laser devices</b>
Mechanism of OSA treatment	Expiratory positive airway pressure	Nasal dilation and mandibular advancement	Provides positive end expiratory pressure breathing capabilities to therapeutic CPAP systems	Various
Sterility	Not sterile	Not sterile	Not sterile	Varies
Expiration dating	None	None	Unknown	Varies
Prescriptio n Use	Yes	Yes	Yes	Yes
At Home Use	Yes	Yes	Yes	Varies

### Performance Data

Bench and clinical performance data were submitted to support the 510(k) Notification. The bench and clinical testing demonstrated that the device is safe and effective for its intended use.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

FEB - 8 2008

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ventus Medical, Inc.  
c/o Cindy Domecus, R.A.C.  
Regulatory Consultant  
1171 Barroilhet Drive  
Hillsborough, CA 94010

Re: K071560

Trade/Device Name: Provent™ Professional Sleep Apnea Therapy

Regulation Number: 21 CFR 872.5570

Regulation Name: Intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea

Regulatory Class: Class II

Product Code: OHP

Dated: January 23, 2008

Received: January 24, 2008

Dear Ms. Domecus:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Malvina B. Eydelman, M.D.  
Director  
Division of Ophthalmic and Ear, Nose  
and Throat Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

**INDICATIONS FOR USE**

510(k) Number (if known): K071560

Device Name: Provent™ Professional Sleep Apnea Therapy

Indications for Use:

The Provent™ Professional Sleep Apnea Therapy device is indicated for use in the treatment of obstructive sleep apnea (OSA).

Prescription Use X AND/OR Over-The-Counter Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE  
IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Karen Baker  
(Division Sign-Off)  
Division of Ophthalmic Ear,  
Nose and Throat Devices

510(k) Number K071560